KEOSYS
MEDICAL IMAGING

K102000

OCT 12 2010

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification for Imagys in conformance with 21 CFR 807.92.

Date Prepared: July 2010.
Submitter: Keosys S.A.S.
1, impasse Augustin Fresnel, Z.A. du Moulin Neuf, B.P. 227
44815 Saint-Herblain cedex, FRANCE
Contact name: Mr. Anthony MOTTIER
Contact Email: anthony.mottier@keosys.com
Contact Telephone: 00 33 (0)2 40 92 26 13
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Device Trade Name: Imagys
Device Common Name: Picture Archiving and Communication System
Device Classification Name: Picture Archiving and Communication System
Classification Panel: 21 CFR §892.2050
Product code: LLZ
Device Classification: Class II
Predicate Devices:

Name	Manufacturer	510(k) number
INTEGRADWeb MPR/MIP	Dynamic Imaging, Inc.	K042313
eFilm Worksattion with Modules	eFilm Medical Inc.	K020995
Visio+ CD Viewer	Keosys S.A.S.	K070606

Device Description:

Imagys is a computing and software solution designed by experts in medical imaging and telecommunications for the collection, quality control, processing, analysis and visualization of imaging data. Imagys can help to execute clinical trials with secure transfer, management, viewing, printing, storage and archiving of data.

Indications for Use:

Imagys (KSNRMAVWRxx, KSNERDxx) is a medical solution for the upload, the secure transfer, the management, the viewing, the reviewing, the printing, the storage and archiving of imaging data, and the related documentations, acquired from a variety of imaging devices. Imagys can also support the management of the imaging parts of a clinical trial workflow including the following steps : quality control, data processing and audit trails. Imagys runs on any standard PC and servers compliant with the Imagys specifications. Typical end users are trained medical professionals and clinical trial actors.

The imaging data can be CT (Computed Tomography), MR (Magnetic Resonance), CR (Computed Radiography), NM (Nuclear Medecine), PET (Positon Emission Tomography), SC (Secondary Capture), US (Ultrasound), XA (Angiographic), video and more DICOM, or others imaging standards, data accepted by the Imagys solution.

It is the user responsibility to check that the ambient luminosity conditions, the images compression ratio and the interpretation monitor specifications are consistent with a clinical diagnostic use of the data.

This device is not indicated for mammography use. Lossy compressed mammography-images and digitized film screen images must not be used for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 mega pixel resolution and meets other technical specifications approved by the FDA.

Testing:

Imagys is tested according to the specifications that are documented in a Software Test Plan. Performance and functional testing are an integral part of Keosys's software development process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 16 2011

Mr. Anthony Mottier
Quality System Manager
Keosys S.A.S.
I, ImpasseAugustin Fresnel, Z.A. du Moulin Neuf, B.P. 227
Saint-Herblsin, 44815
FRANCE

Re: K102000
Trade/Device Name: Imagys
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 12, 2010
Received: July 15, 2010

Dear Mr. Mottier:

This letter corrects our substantially equivalent letter of October 12, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Imagys

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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102000